

## **REMARKS**

Claims 1, 2, 8-12, 15-18, 19, 20, 26-30, 33-36, 37, 38, 44-47, and 49-52 remain in the application. Claims 1, 19, and 37 have been amended. Claims 4, 13, 22, 31, 40, and 48 have been canceled. Claim 53 has been added. Reconsideration of this application, as amended, is respectfully requested.

Claims 1, 19, and 37 have been amended to specify that the at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, that the optical measurement is a spatially resolved diffuse reflectance measurement. Support for these amendments can be found at page 19, line 1 through page 21, line 7, at page 21, line 14 through page 22, line 3, and at page 31, line 9 through page 45, line 28 of the specification and in claims 4, 13, 22, 31, 40, and 48, as originally filed. Claim 37 has been further amended to replace the term "means" in part (a) with the expression "source of light" and the term "means" in part (c) with the term "detector." Support for these changes can be found at page 13, lines 17-23, at page 31, lines 16-21, at page 14, lines 1-5, and at page 32, line 26 through page 33, line 6 of the specification.

Claim 53 has been added to specify that the distance between (a) the source of light for irradiating a region of said biological sample with light and (b) the means for collecting light re-emitted from said region of said biological sample is less than two millimeters. Support for these claims can be found at page 33, line 22 through page 34, line 3 of the specification.

It should be noted that parts (e), (f), and (g) were missing from claim 19 in the APPENDIX OF CLAIMS in the BRIEF ON APPEAL. The previous complete version of claim 19 can be found in the AMENDMENT AND RESPONSE mailed September 18, 2001. It should also be noted that an Information Disclosure Statement was submitted on July 8, 2002 and not considered. Applicants are resubmitting the material in this Information Disclosure Statement at this time. It is requested that the Examiner consider the references in the Information Disclosure Statement.

Claims 1-3, 7-16, 19-21, 25-34, 37-39, 43-46, and 49 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, and 35-36 of U. S. Application Serial No. 09/080,470 to Khalil et al. in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. This rejection respectfully traversed for the following reasons.

Laufer et al., "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" (hereinafter "Laufer et al."), discloses the effect of temperature on the optical properties of human dermis and subdermis as a function of near-infrared wavelength between 25 °C and 40 °C.

Measurements were performed *ex vivo* on a total of nine skin samples taken from the abdomen of three individuals. Laufer et al. utilizes diffuse reflectance and transmission measurements carried out on thin dermis and subdermis samples at four different temperatures by means of an integrating sphere, which was placed in a temperature controlled environment. See page 2479 of Laufer et al.

All of the claims of this application, as amended, require spatially resolved diffuse reflectance measurements of a biological sample. Spatially resolved diffuse reflectance measurements are described in detail at page 21, line 14 through page 22, line 3, and at page 31, line 9 through page 45, line 28 of the specification. This type of measurement is distinguishable from the type of diffuse reflectance and transmission measurements made by Laufer et al. Furthermore, Laufer et al. requires illumination of both sides of the biological sample, because the samples of dermis have different reflectivities from opposite sides. See page 2481, lines 8-9, of 2.3. *Measurement methods* of Laufer et al. and page 2482, line 1 of 3. **Results** of Laufer et al. These statements clearly teach away from the use of intact tissue, because the underside of the dermis, at a depth suitable for spatially resolved diffuse reflectance, cannot be illuminated without invading intact tissue. Invading intact tissue would completely defeat the purpose of the present invention. For these reasons, the obviousness-type double patenting rejection should be withdrawn.

Claims 1-3, 6-21, 24-39, 42-51 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. This rejection is respectfully traversed for the following reasons.

Mills, U. S. Patent No. 5,978,691 (hereinafter "Mills"), discloses a method for facilitating the noninvasive determination of characteristics of subject matter and the environment in which said subject matter exists, the method comprising the steps of:

- Emitting at least one wavelength of electromagnetic radiation applied to said subject matter
- Detecting said wavelength after contact with said subject matter
- Inducing a temperature change in said subject matter while emitting and detecting said radiation applied to said subject matter
- Computing parameters based on information processed from the contact of said radiation at various temperature levels on said subject matter.

As stated previously, Laufer et al. discloses the effect of temperature on the optical properties of human dermis and subdermis as a function of near-infrared wavelength between 25 °C and 40 °C. Measurements were performed *ex vivo* on a total of nine skin samples taken from the abdomen of three individuals. Laufer et al. utilizes diffuse reflectance and transmission measurements carried out on thin dermis and subdermis samples at four different temperatures by means of an integrating sphere, which was placed in a temperature controlled environment.

As stated previously, all of the claims of this application, as amended, require spatially resolved diffuse reflectance measurements of a biological sample. Mills fails to disclose spatially resolved diffuse reflectance measurements of a biological sample. Laufer et al. fails to disclose spatially resolved diffuse reflectance measurements of a biological sample. Furthermore, Laufer et al. requires illumination of both sides of the biological sample, because the samples of dermis have different reflectivities from

opposite sides. See page 2481, lines 8-9, of 2.3. *Measurement methods* of Laufer et al. and page 2482, line 1 of 3. **Results** of Laufer et al. These statements clearly teach away from the use of intact tissue, because the underside of the dermis, at a depth suitable for spatially resolved diffuse reflectance, cannot be illuminated without invading intact tissue. Invading intact tissue would completely defeat the purpose of the present invention. Accordingly, the combination of Mills and Laufer et al. fails to render the claims of this application obvious to one of ordinary skill in the art because neither discloses nor suggests the use of spatially resolved diffuse reflectance measurements of a biological sample.

Claims 4-5, 22-23, and 40-41 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. and in view of U. S. Patent No. 5,782,755 to Chance et al. This rejection is respectfully traversed for the following reasons.

Chance et al., U. S. Patent No. 5,782,755 (hereinafter "Chance '755") discloses a scheme for monitoring one or more solutes in a biological system comprising the steps of: delivering light into a biological system containing one or more solutes, the light having a wavelength selected to be in a range wherein at least one of the one or more solutes is substantially non-absorbing; detecting at least first and second portions of the delivered light, the first portion having traveled through the biological system along one or more paths characterized by a first average path length, and the second portion having traveled through the biological system along one or more paths characterized by a second average path length that is greater than the first average path length; and comparing the first and second portions of the delivered light to monitor a concentration of one or more of the solutes in the biological system.

Claims 5, 23, and 41 have been canceled. With respect to claims 4, 22, and 40, the combination of Mills and Laufer et al. fails to render the claims of this application obvious to one of ordinary skill in the art because neither discloses nor suggests the use of spatially resolved diffuse reflectance measurements of a biological sample. Chance et al. '755 does not disclose or suggest the use of a change in temperature to determine a parameter of a

biological sample or an apparatus that utilizes a change in temperature to determine a parameter of a biological sample. The rejection based on the combination of Mills, Laufer et al., and Chance '755 is improper because the success of that combination could not have been predicted in the absence of Applicants' disclosure. Thus, the rejection based on the combination of Mills, Laufer et al., and Chance '755 is a hindsight reconstruction of the prior art, which reconstruction could have been perceived only after seeing the Applicants' disclosure. It is impermissible to use the inventor's disclosure as a "road map" for selecting and combining prior art disclosures. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. For this reason, the combination of Mills, Laufer et al., and Chance '755 is impermissible, and, consequently, that combination cannot render the claims of this application obvious to one of ordinary skill in the art. Accordingly, the combination of Chance et al. '755, Mills, and Laufer et al. fails to render the claims of this application obvious to one of ordinary skill in the art.

Claim 52 was rejected under 35 U. S. C. § 103 (a) as being unpatentable over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. and in view of U. S. Patent No. 5,873,821 to Chance et al. This rejection is respectfully traversed for the following reasons.

Chance et al., U. S. Patent No. 5,873,821 (hereinafter "Chance et al. '821"), discloses an oximeter disposed on an endoscope, catheter or guidewire or the like for insertion via a body passage to internal tissue, and including means such as an inflatable balloon to press the oximeter sensor against the localized tissue of interest.

The combination of Mills and Laufer et al. fails to render the claims of this application obvious to one of ordinary skill in the art because neither discloses nor suggests the use of spatially resolved diffuse reflectance measurements of a biological sample. Chance et al. '821 fails to remedy the

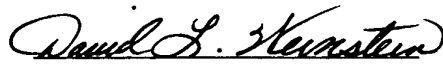
deficiencies of the combination of Mills and Laufer et al., because Chance et al. '821 fails to disclose or suggest spatially resolved diffuse reflectance. Accordingly, the combination of Chance et al. '821, Mills, and Laufer et al. fails to render claim 52 obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1, 2, 8-12, 15-18, 19, 20, 26-30, 33-36, 37, 38, 44-47, and 49-52, as amended, and new claim 53 are in condition for allowance, and official Notice of Allowance is respectfully requested.

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